REMARKS

Reconsideration of the present application in light of the above amendments and following remarks is respectfully requested. Claims 73-81 are pending and claim 73 stands allowed. As set forth above, certain claims have been amended, for purposes of clarity and to advance prosecution of the subject application, such that the claimed polypeptides are directed to specific polypeptide sequences of SEQ ID NO: 392, as well as related polypeptides that retain the ability to cross-react with an antibody that is specific for SEQ ID NO: 392. Support for these amendments can be found, for example, at page 16, line 16 to page 17, line 22, page 22, line 20 to page 23, line 4, and elsewhere in the specification as originally filed.

The above amendments are made for purposes of clarity and to advance prosecution. Such amendments are not to be construed as acquiescence to any stated ground for rejection and are made without prejudice to prosecution of subject matter modified and/or removed by the amendment in a related divisional, continuation and/or continuation-in-part application.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 74-81 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. More particularly, the Action asserts one of skill in the art would not be able to practice the invention without undue experimentation, allegedly due to "an enormous number of polynucleotides, vectors, and host cells to be experimentally tested in order to make a useful polypeptide" of the claimed compositions. The Examiner further asserts that the art of polypeptide usage utilizes polypeptides via some type of enzymatic activity or binding activity and that claims 74-81 lack citation of any such usefulness or activity limitation.

Applicants respectfully traverse this rejection and submit one of skill in the art, at the time the application was filed, could fully make and use the claimed invention upon review of the instant specification without undue experimentation.

The scope of enablement of a particular invention "is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art." See

Invitrogen v. Clontech Lab., Inc., 429 F.3d 1052, 1070-1071 (Fed. Cir. 2005) (internal citations omitted). Indeed, a patent disclosure "need not enable information within the knowledge of an ordinarily skilled artisan, but instead preferably omits from the disclosure any routine technology that is well known at the time of the application." See *Chiron v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir.2004) (internal citation omitted). Thus, "an enabling disclosure need not describe how to make and use *every possible variant* of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and even extrapolate beyond the disclosed embodiments...". See *Chiron* at 1253 (emphasis added). As such, the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied if the description enables any mode of making and using the invention. See *Invitrogen* at 1071.

In the present application, Applicants have described SEQ ID NO: 392 as an extended form of a polypeptide referred to as O8E, encoded by SEQ ID NO: 391, and derived from a cDNA sequence identified using an approach known as serological expression cloning. This approach was designed and implemented by Applicants to facilitate the identification of immunogenic proteins expressed by ovarian cancer cells (*e.g.*, Example 1). Subsequent microarray expression analysis confirmed that O8E exhibits an ovarian cancer-associated expression pattern (*e.g.*, Example 2). In addition, antibodies raised against E. coli-expressed recombinant O8E were tested for antibody epitope recognition against 20- and 21-mer peptides that span the O8E protein and, in this way, antibody epitopes corresponding to amino acid sequences of O8E recognized by affinity purified anti-O8E antibodies were identified (*e.g.*, Example 3). Further O8E-specific antibodies were generated by Applicants and used to demonstrate that O8E is a cell surface-expressed protein (*e.g.*, Examples 6 and 7), which offers a number of advantages in the context of protein- and antibody-based indications. Thus, O8E was identified by Applicants based upon its immunogenicity in a serological expression cloning approach and its ovarian cancer-associated expression pattern was confirmed; O8E polypeptides were produced by standard recombinant methods; O8E-specific antibodies were generated; and epitopes for a number of O8E-specific antibodies were mapped.

The present application is also replete with illustrative guidance concerning various modes for making and using the claimed O8E polypeptides and compositions, all of which are well within the general purview considered to be routine techniques for a skilled artisan in the area to which this invention pertains. For example, the instant specification provides that polypeptides of the invention, as well as variants and fusions thereof, may be prepared by any of a variety of well-known techniques, including using a disclosed O8E polynucleotide sequence for generating any desired length of the corresponding sequence, *e.g.*, by Polymerase Chain Reaction (PCR), combined with using known expression vectors (including plasmids, phagemids, lambda phage derivatives, cosmids, etc.) and known host cells (such as *E.coli*, yeast or mammalian cells including COS or CHO cells) in order to generate the claimed polypeptides of the present invention (*e.g.*, page 11, line 26 to page 12, line 17). These and other methods for recombinant protein production were indeed well known and easily practiced by one of skill in the art at the time this application was filed.

The present application further describes how the claimed polypeptides can be used to generate antibodies specific for O8E polypeptide of SEQ ID NO: 392 and how such antibodies can be used in any of a number of diagnostic and/or pharmaceutical embodiments. For example, antibodies specific to the claimed polypeptides of the invention can be generated and used for detecting the presence of ovarian cancer cells that express O8E, for targeting therapeutic or other agents to the surface of O8E-expressing cells (*e.g.*, page 23, lines 5-17, page 23, lines 10-17).

In view of Applicants' disclosure, taken in combination with what is well known in the art, a skilled individual would easily understand how to make O8E polypeptides of SEQ ID NO: 392, as well as antibodies specific for SEQ ID NO: 392. A skilled artisan would also understand, in view of this disclosure, that the genus of polypeptides encompassed the current claims are also adequately enabled by the specification. More particularly, the skilled artisan, upon accepting that SEQ ID NO: 392 can be used to make diagnostic and/or pharmaceutical antibodies, would also understand that the claimed genus of polypeptides bearing structural identity to SEQ ID NO: 392 could be made and used in the very same context and to the same extent as the specific species of SEQ ID NO: 392, despite the fact that they are not identical to

the species of SEQ ID NO: 392. For example, based upon fundamental principles of immunological recognition and antibody cross-reactivity, it would be understood that the claimed genus of polypeptides of SEQ ID NO: 392 can be made and used, without undue experimentation, to generate antibodies that are cross-reactive with the specifically disclosed species of SEQ ID NO: 392, and are thus useful in the context of Applicants' disclosure in the same manner as for SEQ ID NO: 392. As the skilled individual would understand and concur that such polypeptides and variants of SEQ ID NO: 392 can be readily and routinely made, and their cross-reactivity with antibodies specific for SEQ ID NO: 392 evaluated and confirmed, they are submitted to fall squarely within the scope of subject matter enabled by the instant disclosure.

With respect to the Examiner's assertion that Applicants have not identified a function or activity of the claimed polypeptides allegedly required to support the breadth of the present claims, Applicants respectfully disagree and submit that the identification of a function of the O8E protein is not required in order to enable the currently claimed invention. All that is required is that a skilled artisan be offered sufficient guidance to make and use the claimed polypeptides, and antibodies thereto in the detection and/or targeting of ovarian cancer cells, which they have done. Protein function in this instance is irrelevant.

The Action appears to veil a utility rejection in its enablement rejection, which is submitted to be improper. Only a single asserted utility is needed for patentability, and such asserted utility is presumed sufficient absent evidence to the contrary. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995). Since the Action has not set forth any evidence to dispute Applicants' disclosed utilities, the claimed polypeptides are presumed to have at least one utility that is sufficient for patentability. Nevertheless, Applicants submit the instant specification provides for multiple utilities for the claimed polypeptides, as discussed above, for generating antibodies to detect and/or target cancer cells.

Finally, Applicants note that the number of available options for vectors and host cells that may be used to produce the claimed compositions bears little pertinence to whether one of skill in the art could practice the claimed invention since the options in question are clearly routine procedures for the skilled artisan and could be practiced using only routine methodologies.

Applicants respectfully urge that a skilled individual, in light of the guidance set forth in the instant specification, and further in view of the level of general knowledge in this art, would know how to make and use Applicants' claimed polypeptides and compositions without undue experimentation and with a reasonable expectation of success. Reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 74-81 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not complying with the written description requirement. In particular, the Action alleges the specification fails to provide a basis for the genus of the claimed polypeptides. The Action further alleges the present application fails to provide for a structure-function relationship that identifies characteristics of the genus polypeptide members not specifically disclosed.

Applicants respectfully traverse this rejection.

The U.S.P.T.O. has indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an applicant discloses functional and/or descriptive information concerning the specie(s) in an application, *e.g.*, a distinguishing identifying characteristic common among the members of a claimed genus (see Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement – Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111).

Applicants' disclosure more than adequately meets this burden. Biological function/activity is clearly but one example of an identifying characteristic sufficient to support a claimed genus of polypeptides. Under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099, at 1106 (emphasis added). Examples of such

identifying characteristics include complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, etc. (*e.g.*, at 1106). In addition, for biomolecules, illustrative identifying characteristics may include a sequence, structure binding affinity, *binding specificity*, molecular weight, etc. (*e.g.*, at 1110).

Indeed, Applicants submit that a single identifying characteristic shared by members of the currently claimed genus is their ability to generate antibodies specific for SEQ ID NO: 392, and the use of such antibodies, for example in detecting and/or targeting ovarian cancer cells. Again, the biological function of the polypeptide of SEQ ID NO: 392 is not relevant to the specificity or immunogenicity of O8E in ovarian cancer cells or to its ability to be used to generate O8E-specific antibodies. Further, an understanding by the skilled artisan that such polypeptides were within Applicants' possession at the time of filing is submitted to be soundly based upon fundamental immunological principles, namely that polypeptides related to, but not identical with, SEQ ID NO: 392, can nonetheless be used to generate antibodies that are cross-reactive with Applicants' species of SEQ ID NO: 392, and are thus useful in the detection and/or targeting of ovarian cancer cells according to Applicants' disclosure. In this respect, to accept the Examiner's position that Applicants were only in possession of the specific species of SEQ ID NO: 392 would improperly exclude an important class of polypeptides structurally related to SEQ ID NO: 392 that the skilled individual would understand were in Applicants' possession, and useful in accordance with Applicants' disclosure, at the time of filing.

Reconsideration of the Examiner's rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090. All of the claims remaining in the application are believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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